IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

MEDPOINTE HEALTHCARE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C. A. No. 06-164-SLR
	)	
APOTEX INC. AND APOTEX CORP.,	)	**REDACTED**
	)	
Defendants.	)	

MEDPOINTE'S OPENING BRIEF ON CLAIM CONSTRUCTION ISSUES

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INTRODUCTION

Pursuant to the Court's June 5, 2007 Amended Rule 16 Scheduling Order (D.I. 85), Plaintiff MedPointe Healthcare, Inc. ("MedPointe") respectfully submits this opening brief in support of its proposed claim constructions.

NATURE AND STAGE OF THE PROCEEDINGS

MedPointe brought this patent infringement action against Apotex Inc. and Apotex Corp. (collectively, "Apotex") based on Apotex's submission of Abbreviated New Drug Application ("ANDA") 77-954 to the U.S. Food and Drug Administration ("FDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Apotex's ANDA seeks the FDA approval necessary for Apotex to engage in the commercial manufacture, use, offer for sale and sale of a generic azelastine hydrochloride nasal spray product prior to the expiration of MedPointe's U.S. Patent No. 5,164,194 ("the '194 patent"). MedPointe contends that Apotex's submission of ANDA 77-954 to the FDA, including its "Paragraph IV Certification" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A). Furthermore, if Apotex commercially makes, uses, offers to sell or sells its proposed generic product within the United States, or imports it into the United States, or induces or contributes to such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

In accordance with the Court's June 5, 2007 Amended Rule 16 Scheduling Order (D.I. 85), the parties exchanged their preliminary proposed claim constructions on October 29, 2007. The parties subsequently met and conferred to reduce the number of claim terms and phrases in dispute. On November 28, 2007, the parties submitted a Joint Claim Construction Statement (D.I. 101) providing their joint-proposed constructions for undisputed claim terms and providing their competing proposed constructions for disputed terms.

SUMMARY OF THE ARGUMENT

For each of the disputed claim terms requiring construction, MedPointe proposes constructions that rely on the plain and ordinary meaning of the claim term as it would be understood by a person of ordinary skill in the art when read in the context of the specification. MedPointe's proposed constructions are fully consistent with the disclosure contained in the specification, as required by the Federal Circuit's decision in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

Apotex, by contrast, proposes constructions that are not supported by the plain and ordinary meaning or by intrinsic or extrinsic evidence. Indeed, Apotex seeks to redefine the claim terms in ways never envisioned by those of ordinary skill. And for good reason. Under a proper claim construction, Apotex's generic product infringes the '194 patent and that patent is valid. Apotex offers contorted claim constructions that often bear no relation to the subject matter of the '194 patent in an effort to manufacture non-infringement and invalidity arguments where there are none.

After considering the intrinsic and extrinsic evidence discussed in detail below, MedPointe respectfully requests that the Court adopt its proposed construction for each of the disputed claim terms and phrases in the form attached as Ex. A.

ARGUMENT

I. Legal Standards For Construing Patent Claims

As the Federal Circuit has explained, "The starting point for any claim construction must be the claims themselves." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). "[T]he words of a claim 'are generally given their ordinary and customary meaning,'" which is the "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the filing date of the patent application."

Phillips v. AWH Corporation, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313. Additionally, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. "[T]he context in which a term is used in the asserted claim can be highly instructive." *Id.* "Differences among claims can also be a useful guide in understanding the meaning of particular claim terms." *Id; see also Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1123 (Fed. Cir. 2004) ("'different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope'").

The *Phillips* court emphasized that "claims must be read in view of the specification, of which they are a part." *Phillips*, 415 F.3d at 1315 (internal quotations and citation omitted). "[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of the disputed term." *Id.* (internal quotations and citation omitted); *On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1337-38 (Fed. Cir. 2006) (stating "the court in *Phillips*, resolving conflict, stressed the dominance of the specification in understanding the scope and defining the limits of the terms used in the claim"). As the Federal Circuit explained, "'the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim.'" *Phillips*, 415 F.3d at 1316 (quoting *Renishaw PLC v. Marposs Societa per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)). As the *Phillips* court concluded, "'The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.'" *Id.*

(quoting *Renishaw*, 158 F.3d at 1250).

The patent's prosecution history is also relevant. "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Id.* at 1317. Prior art cited in a patent or in its prosecution history also constitutes intrinsic evidence. *See Kumar v. Ovonic Battery Co., Inc.*, 351 F.3d 1364, 1368 (Fed. Cir. 2003).

Courts may also rely on extrinsic evidence, such as expert testimony, dictionaries and learned treatises, to provide background on the technology at issue, to explain how an invention works, or to explain the meaning of a term as it would be understood by one of ordinary skill in the art. *See Phillips*, 415 F.3d at 1317-18. "Extrinsic evidence, however, cannot be used to alter a claim construction dictated by a proper analysis of the intrinsic evidence." *On-Line Tech. v. Bodenseewerk Perkin-Elmer*, 386 F.3d 1133, 1139 (Fed. Cir. 2004) (citing *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1367 (Fed.Cir.2003) for the proposition that "[w]hen an analysis of intrinsic evidence resolves any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence to contradict the meaning so ascertained.")

II. The '194 Patent

MedPointe's '194 patent discloses and claims a method of treating various types of rhinitis and/or conjunctivitis by applying the compound azelastine directly to the nose or eyes. By 1988, when the application leading to the '194 patent was filed, the compound azelastine was known to have antihistaminic properties when administered orally, but was also known to have an exceptionally bitter taste. Azelastine tastes so bad that, as reported in the '194 patent, it actually perverts the sense of taste, Ex. B, col. 1, ll.66-68, a medical condition known as dysgeusia.

Given this situation, a person of ordinary skill in the art would not have pursued the claimed nasal and ocular preparations of azelastine. Indeed, the last thing one would want to do

with an exceptionally bitter tasting compound like azelastine is dissolve it in a solution to be administered directly to the nose or eyes, where it would be tasted. Moreover, the prior art cited by MedPointe in the '194 patent showed that oral administration of azelastine resulted in higher antihistaminic activity than non-oral administration, and presented much more active compounds for non-oral administration.

Azelastine's exceptionally bad taste and reduced activity when administered other than orally taught away from the claimed formulations. There were also a number of other factors that taught away. For example, by 1988, many antihistamines were known to cause dangerous side effects when applied directly in the nose like ciliotoxicity and, in some instances, tissue necrosis. Antihistamines were also known to be ineffective when administered in this fashion.

As a result, those of ordinary skill in the art in 1988 would not have had any reason to believe that azelastine could be used for direct application formulations. Researchers collaborating with MedPointe, however, made the surprising discovery that it could. In particular, they discovered that spraying azelastine directly on nasal tissues is uniquely safe, efficacious and well-tolerated by patients. This is demonstrated by the tremendous success of MedPointe's nasal spray product, Astelin®, which had sales over $167 million in 2006.

Hoping to profit from MedPointe's innovation, Apotex seeks to copy MedPointe's highly successful Astelin® product. MedPointe asserts that Apotex's proposed generic azelastine nasal spray product infringes Claims 4, 5, 7, 8 and 9 of the '194 patent. MedPointe respectfully requests that the Court construe the disputed claim language in these patents in accordance with MedPointe's proposed constructions as set forth below.

III. MedPointe's Proposed Claim Constructions

A. "Irritation Or Disorders Of The Nose And Eye"

The phrase "irritation or disorders of the nose and eye" appears in Claims 4, 5, 7, 8 and 9

of the '194 patent and should be construed to mean "Rhinitis and/or conjunctivitis, including seasonal allergic rhinitis and vasomotor rhinitis. Symptoms of rhinitis include itching (also known as "pruritus"), sneezing, increased secretions (also known as "rhinorrea"), and congestion." MedPointe's proposed construction is supported by the ordinary meaning, the specification and the prosecution history.

A person of ordinary skill in the art would understand the claim term "irritation or disorders of the nose and eye" to be limited to rhinitis and/or conjunctivitis. Those are the only irritations or disorders of the nose and eye that the specification and prosecution history contemplate or disclose.[1] Treatments for an "irritation or disorder[] of the nose and eye" that is not related to rhinitis or conjunctivitis, such as a deviated septum or nearsightedness, are not even discussed in the specification.

The '194 patent discusses treatment for "allergy-related rhinitis," "normal common cold (caused, for example, by rhino viruses)," and "vasomotor cold and the symptoms of illness triggered thereby," which are all types of rhinitis. Ex. B, col. 1, ll. 40-43. The patent also discusses treatment for "non-specific conjunctivitis" and "allergy-related conjunctivitis," which are both types of conjunctivitis. *Id.* at col. 1, ll. 50-51. The patent also mentions a symptom of conjunctivitis called "allergic blepharoedema," *id.* at col. 1, l. 51, which is inflammation of the eyelid (that is lined by the conjunctiva). *See* Ex. D, The Random House Dictionary of the English Language 222, 620 (2d ed. 1987). The same paragraph of the specification further mentions "catarrhal conditions in the eye or nose," which is another type of conjunctivitis or

[1] "Rhinitis means inflammation of the mucous membrane of the nose." Ex. C, Black's Medical Dictionary 589 (35th ed. 1987). Analogously, "conjunctivitis" is defined as "inflammation of the conjunctiva," which is "the mucous membrane that lines the exposed portion of the eyeball and inner surface of the eyelids." Ex. D, The Random House Dictionary of the English Language 431 (2d ed. 1987).

rhinitis, respectively.[2] *Id.*, at col. 1, l. 52. Lastly, the specification mentions "coryza," which is a type of rhinitis.[3] *Id.*, at col. 1, l. 52.

The prosecution history confirms that the disputed claim term should be limited to rhinitis and/or conjunctivitis. The prosecution history recites that the "present invention . . . . produces elimination or marked relief in allergy-related rhinitis, the common cold, and vasomotor cold." Ex. E, MP0113. Moreover, to overcome an obviousness rejection, the applicant relied on a declaration that reported on the invention's effectiveness in a rhinitis model. According to the declaration, "[t]he experiments are based on the fact that an allergic reaction in the eyes or the nose results from the liberation of histamine from mast cells. . . . ***The liberated histamine causes rhinitis symptoms***. The effectiveness of azelastine in preventing these symptoms in the eyes and the nose can be determined by measuring its effectiveness in preventing the liberation of histamine from sensitized rat peritoneal mast cells. . . . [a]zelastine was about twice as effective . . . . For this reason, it is submitted that the claimed process is unobvious." *Id.* at MP0056, MP0063-64 (emphasis added).

Furthermore, extrinsic evidence demonstrates that a person of ordinary skill in the art would understand the phrase "irritation or disorders of the nose and eye" in the context of the patent to mean rhinitis and/or conjunctivitis, and no other irritation or disorder of the nose and eye.

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[2] "Catarrh" is defined as an "inflammation of a mucous membrane, esp. of the respiratory tract, accompanied by excessive secretions." Ex. D, The Random House Dictionary of the English Language 326 (2d ed. 1987).

[3] "Coryza" is defined as an "acute inflammation of the mucous membrane of the nasal cavities." Ex. D, The Random House Dictionary of the English Language 456 (2d ed. 1987).

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Additional extrinsic evidence supports MedPointe's proposed construction. *See, e.g.*, Ex. R, Allergic Diseases: Diagnosis and Management 207 (3d ed. 1985) ("Seasonal allergic rhinitis . . . is characterized mainly by watery rhinorrhea, nasal congestion, sneezing, and pruritus of the eyes, nose, ears, and throat."); Ex. S, Allergic Diseases: Diagnosis and Management 198 (2d ed. 1980) ("Patients with vasomotor rhinitis complain of chronic nasal congestion, rhinorrhea, and sneezing.").

The Court should reject Apotex's proposed construction because it is contrary to the specification, prosecution history and extrinsic evidence. Apotex agrees that the claim term "irritation or disorders of the nose and eye" includes "rhinitis and/or conjunctivitis, including seasonal allergic rhinitis and vasomotor rhinitis." But Apotex also asks the Court to rule that the term "***is not limited to***" these conditions. This open-ended proposal should be rejected. Nothing in the specification or the prosecution history suggests a treatment for an irritation or disorder of the nose and eye other than those associated with rhinitis or conjunctivitis. Apotex's proposed construction seeks improperly to extend the scope of the claims beyond the specification in a

transparent attempt to jeopardize their validity. The Court should reject these tactics, which will only lead to uncertainty about the claim's true scope at trial and on appeal.

For at least these reasons, MedPointe respectfully requests that the Court construe the phrase "irritation or disorders of the nose and eye " in Claims 4, 5, 7, 8 and 9 of the '194 patent to mean: "Rhinitis and/or conjunctivitis, including seasonal allergic rhinitis and vasomotor rhinitis. Symptoms of rhinitis include itching (also known as "pruritus"), sneezing, increased secretions (also known as "rhinorrea"), and congestion."

B. "Applying Directly To Nasal Tissues Or To The Conjunctival Sac Of The Eyes"

The phrase "applying directly to nasal tissues or to the conjunctival sac of the eyes" in Claims 4, 5, 7, 8 and 9 of the '194 patent should be construed to mean "Topical application to the nose or to the conjunctival sac of the eyes. Excludes oral and parenteral applications." Once again, MedPointe's definition is supported by the plain and ordinary meaning, the specification and prosecution history of the '194 patent.

The dictionary definition of "apply" is to "lay or spread on." Ex. D, The Random House Dictionary of the English Language 102 (2d ed. 1987). The dictionary definition of "directly" is "immediately" and "without intervening space." *Id.* at 559. The immediate physical application of the active compound would be a topical application to the nose or to the conjunctival sac of the eyes, as MedPointe's proposed construction requires. Thus, MedPointe's proposed construction reflects the plain and ordinary meaning of the disputed claim term.

Moreover, the specification states that the invention is related to "azelastine... formulations [as] applied directly in the nose and/or to the conjunctival sac of the eye." Ex. B, col. 1, ll. 34-38. All of the examples in the specification, consequently, involve the topical application by either "spray[ing] into the nose," "dripp[ing] into the nose or eye," "applying the

ointment into the nose" or "introduction of the active substance into the nose of the patient." *Id.* at col. 6, ll. 30, 34-35, 56 and col. 7, ll. 19-20. Similarly, the applicant stated in the prosecution history that the "claims recite that azelastine is applied 'directly to nasal tissues or to the conjunctival sac of the eye.'" Ex. E, MP0092. The applicant further stated that the invention was "based on a surprising discovery that azelastine and its physiologically acceptable salts display advantageous and surprising effects when applied directly in the nose and/or to the conjunctival sac of the eye." *Id.* at MP0113.

The exclusion of oral and parenteral application in MedPointe's proposed construction is required by the specification and prosecution history. The specification excludes oral administration from the scope of the claims. For example, the specification indicates that there were problems associated with oral application and that they were overcome by the topical applications disclosed in the patent. The Federal Circuit has held that subject matter criticized in the specification is excluded from the scope of the claims. *See, e.g., Honeywell Intern., Inc. v. ITT Industries, Inc.*, 452 F.3d 1312, 1320 (Fed. Cir. 2006) ("the written description has gone beyond expressing the patentee's preference for one material over another. Its repeated derogatory statements concerning one type of material are the equivalent of disavowal of that subject matter from the scope of the patent's claims.") According to the patent, "the invention provides a way to overcome problems which arise because of azelastine's exceptionally penetrating bitter taste. . . . This problem has hitherto prevented oral application of azelastine solutions, since patients refuse to take such azelastine solutions or suspensions." Ex. B, col. 1, ll. 56-63.

The prosecution history also excludes oral and parenteral application from the scope of the claims. For example, the applicant distinguished the invention of the '194 patent from the

prior art because the prior art disclosed only parenteral and oral applications of azelastine, rather than direct application to nasal tissues or to the eye. In response to an Examiner's office action, the applicant represented that the "only routes of administration actually disclosed in Vogelsang [prior art] are subcutaneous (parenteral) and oral. There is no evidence that azelastine would be effective when applied directly to nasal tissues or to the eye. The advantages of the present invention relate to a different mode of administration, but there is no suggestion of them in this reference." Ex. E, MP0095.

Apotex's proposed definition is contrary to the plain language of the claim, specification and the prosecution history. Apotex takes the doubly flawed position that the phrase "applying directly to nasal tissues ***or*** to the conjunctival sac of the eyes" somehow means "***including but not limited to*** application directly to mucous membranes of the nose ***and*** eye." Contrary to Apotex's proposed construction, the claim language could not be more clear that the treatment can only be delivered to the nose ***or*** eyes at any one time, not both. Apotex's proposed construction has no support in the patent specification. *See, e.g.*, Ex. B, Abstract ("A medicament for ***nasal use or for use in the eye*** which contains as active ingredient azelastine or a physiologically acceptable salt.") (emphases added).

Apotex's proposed construction is, at best, ambiguous on this point and can be rejected on that basis alone. There is similarly no support in the prosecution history to include application of the medicament to areas other than the nose and eyes, which Apotex's proposed construction would allow with its "including but not limited to" language. As stated above, the applicant distinguished the '194 invention from the prior art on the basis that "[the prior art] reference simply does not disclose the step of administering azelastine 'directly to nasal tissue or to the conjunctival sac of the eye.'" Ex. E, MP0093-94. Thus, the term "applying directly to nasal

tissues ***or*** to the conjunctival sac of the eyes" should require direct application to at least one of these tissues and exclude other methods of administration.

For at least these reasons, MedPointe respectfully requests that the Court construe the "applying directly to nasal tissues or to the conjunctival sac of the eyes" phrase in Claims 4, 5, 7, 8 and 9 of the '194 patent to mean: "Topical application to the nose or to the conjunctival sac of the eyes. Excludes oral and parenteral applications."

C. "Azelastine And Its Physiologically Acceptable Salts"

The phrase "azelastine and its physiologically acceptable salts" in Claims 4, 5, 7, 8 and 9 of the '194 patent should be construed to mean "Azelastine and salts of azelastine that are physiologically safe, effective, and tolerable, such as azelastine hydrochloride." MedPointe's proposed construction is supported by the plain meaning and ordinary meaning of the claim term and the specification.

The specification discloses that "the object of the present invention is to provide a ***well tolerated and improved remedy*** based on azelastine or its salts for the treatment both of the allergy-related and vasomotor-related conditions as well as rhino virus-related cold and its accompanying symptoms." Ex. B, col. 2, ll. 3-8. The term "improved remedy" entails both safety and efficacy of the treatment, whereas the term "well-tolerated" entails tolerability.

The dictionary definition of "physiology" also supports that the "physiologically acceptable" portion of the disputed claim term entails a treatment that is safe, effective, and tolerable. Physiology is "the branch of medical science that deals with the healthy functions of different organs, and the changes that the whole body undergoes in the course of its activities." Ex. C, Black's Medical Dictionary 540 (35th ed. 1987). Therefore, a salt that is "physiologically acceptable" must not only avoid inhibiting the healthy functioning of different organs, but also maintain the assistance provided by azelastine to their healthy functioning. In other words, a

physiologically acceptable salt of azelastine must be safe, effective and tolerable.

Apotex proposes a definition wherein "physiologically acceptable" refers to "[a] salt form of azelastine capable of being administered to an animal." Once again, Apotex's proposed construction bears no relation to the disclosure contained in the specification. A toxic salt form may be administered to an animal, but that is the antithesis of the invention. Physiologic acceptability is a more limited and precise concept than mere capability to deliver a drug without regard to its consequences. Apotex's proposed construction also ignores the fact that the invention is designed to provide a safe, effective and tolerable dosage of drug to ***human beings***. For example, the patent discuss the tolerability of azelastine in terms of human taste. *See* Ex. B, col 1, ll. 63-66 ("It was surprisingly found in trial subjects that this bitter taste was no longer in evidence when the azelastine formulations of the invention were sprayed into the nose."). This demonstrates that the "physiological[] acceptab[ility]" must relate to ***human*** acceptability, not acceptability to members of the animal kingdom.

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Lastly, Apotex's construction again suffers from the "including but not limited to" problem. This legalese has the potential to create unnecessary disputes at trial and on appeal regarding the true scope of the claims and should be rejected.

For at least these reasons, MedPointe respectfully requests that the Court construe the phrase "azelastine and its physiologically acceptable salts " in Claims 4, 5, 7, 8 and 9 of the '194 patent to mean: "Azelastine and salts of azelastine that are physiologically safe, effective, and tolerable, such as azelastine hydrochloride."

D. "A Medicament"

The term "a medicament" in Claims 4, 5, 7, 8 and 9 of the '194 patent should be construed to mean "A product that includes a medicinal substance that has acceptable safety, efficacy, and tolerability for use in humans." MedPointe's proposed construction is the plain and ordinary meaning of that term. Moreover, MedPointe's proposed construction is supported by the testimony of Apotex's experts.

The dictionary definition of the term "medicament" is "a healing substance; medicine; remedy." Ex. D, The Random House Dictionary of the English Language 1194 (2d ed. 1987). If a product is to be a "healing substance," "medicine" or "remedy," it must be able to be administered (tolerability) and improve health (efficacy) without causing a simultaneous detriment (safety). In other words, it must be safe, effective and tolerable.

MedPointe's proposed construction is also supported by the testimony of Apotex's

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Apotex again proposes a construction that lacks support in the patent. Apotex proposes that "a medicament" should be construed to mean a preparation "which includes but is not limited to a formulation containing excipients, preservatives ***and/or*** active ingredients" (emphases added). Under Apotex's proposed construction, "a medicament" need not contain any active ingredient at all. This is plainly wrong and wholly unsupported by the specification. As explained in therein, the '194 patent "relates to the treatment of nasal and eye tissues with azelastine." Ex. B, col. 1, ll. 6-7. For this reason alone, the Court should reject Apotex's proposed claim construction.

Apotex's proposed construction also again suffers from the "includes but is not limited to" problem. As before, this language will cause unnecessary debates regarding claim scope in later proceedings and should be rejected. For example, contrary to Apotex's proposed definition, nowhere does the patent suggest a therapy combining azelastine with any other active ingredient. *See* Ex. B, Abstract ("A medicament . . . which contains ***as active ingredient azelastine or a physiologically acceptable salt***") (emphases added); col. 2, ll. 3-5 ("the object of the present invention is to provide a well tolerated and improved remedy ***based on azelastine or its salts***...")

(emphases added); col. 6, ll. 7-9 ("Example 1: Nasal spray or nasal drops or eye drops with 0.1% ***azelastine hydrochloride as active ingredient***") (emphases added). Similarly, nowhere does the prosecution history suggest a therapy combining azelastine with any other active ingredient. Ex. E, MP0113 ("The invention is claimed in claim 1 as ***a method which comprises applying azelastine*** directly to the nasal tissues or to the conjunctival sac of the eye.") (emphases added); MP0102, MP0114 ("The ***claims relate to administration of azelastine*** directly into nasal and eye tissues.") (emphases added).

Apotex attempts to load the rest of its construction with unnecessary verbiage to prop up its invalidity arguments. But there is no need or basis to construe "a medicament" in this fashion.

Furthermore, Apotex's extended constructions for the term "a medicament" are improper because they propose different meanings for the same claim term in different claims. For instance, contrary to its construction of "a medicament" in Claims 1 through 8, Apotex further limits its proposed construction of that term in Claim 9 to "solutions (including aqueous solutions), suspensions, and powders." It is axiomatic that claim terms should be construed consistently throughout the patent. *Phillips v. AWH Corporation*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (stating that "claim terms are normally used consistently through the patent"). Apotex's proposed construction allows for the untenable result that the same drug product could be "a medicament" for Claims 1-8, but not "a medicament" for Claim 9. Apotex's proposed claim constructions can again be rejected for this reason alone.

Further confirming the impropriety of Apotex's disparate construction of "a medicament" in Claim 9, the subsequent phrase "applied by spraying" in Claim 9 requires the use of an aqueous solution, and thereby cannot refer to non-aqueous solutions, suspensions or powders, as

Apotex's proposed construction would allow. The specification provides:

> The preferred embodiment of the invention is a ***sterile and stable aqueous solution*** of azelastine or one or more of its salts which can be used in the form of drops, ointments, creams, gels, insufflatable powders or, ***in the particularly preferred embodiment, in the form of a spray (preferably a nasal spray).***

Ex. B, col. 2, ll. 12-17 (emphases added). In addition, Example 1 of the '194 patent supports that "applied by spraying" refers to an aqueous solution. *See id.* at col. 6, ll. 19-31 ("The solution obtained is diluted . . . with water . . . . azelastine hydrochloride [is] sprayed into the nose . . . in the form of a solution."). In contrast, Example 3 of the '194 Patent teaches that application by a dosage aerosol, which is different from a spray because it is packaged under pressure and contains propellants, refers to a suspension. *Id.* at col. 5, ll. 23-28; col. 7, ll. 12-15. The Court should reject Apotex's proposed constructions that conflate the two different methods of delivering azelastine.

The prosecution history of the '194 patent also supports that "a medicament," which is "applied by spraying" in Claim 9, cannot include a powder. The applicant stated that: "The invention is claimed in claim 1 as a method which comprises applying azelastine directly to the nasal tissues or to the conjunctival sac of the eye. Claims 2-8 relate to more preferred features of the pharmaceutical compositions containing azelastine which is applied in accordance with the method of claim 1. ***Claims 9-11 relate to more preferred modes of application*** of the azelastine-containing composition." Ex. E, MP0113 (emphases added). Since Claims 9, 10 and 11 relate to "modes of application" by spraying, drops, and powders, respectively, "applying by spraying" cannot include applying by powder, as Apotex's proposed construction allows. Otherwise, the claims would not be different and would violate the doctrine of claim differentiation. *See Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*,

381 F.3d 1111 (Fed. Cir. 2004) ("'different words or phrases used in separate claims are

presumed to indicate that the claims have different meanings and scope'").

Extrinsic evidence further demonstrates that a person of ordinary skill in the art would understand "applied by spraying" to be limited to aqueous solutions, as opposed to non-aqueous solutions, suspensions or powders. *See* Ex. I, Remington's Pharmaceutical Sciences (1985) at 1500 ("Nasal solutions are usually ***aqueous solutions*** which are designed to be administered to the nasal passages in drops or ***spray form***.") (emphases added).

For at least these reasons, MedPointe respectfully requests that the Court construe the phrase "a medicament" in Claims 4, 5, 7, 8 and 9 of the '194 patent to mean: "A product that includes a medicinal substance that has acceptable safety, efficacy, and tolerability for use in humans."

E. "The Medicament Contains 0.003 to 0.5% (Weight/Weight) Of Azelastine Or An Amount Of A Physiologically Acceptable Salt Of Azelastine Which Contains 0.003 To 0.5% (Weight/Weight) Azelastine"

The phrase "the medicament contains 0.003 to 0.5% (weight/weight) of azelastine or an amount of a physiologically acceptable salt of azelastine which contains 0.003 to 0.5% (weight/weight) azelastine" in Claim 4 of the '194 patent should be construed to mean "The medicament contains 0.003 to 0.5% (weight/weight) of azelastine or an amount of a physiologically acceptable salt of azelastine in which the weight of azelastine base is 0.003 to 0.5% of the weight of the medicament. Includes a 0.0033 to 0.55% (weight/volume) aqueous solution of azelastine hydrochloride."

The parties agree that the phrase applies to azelastine and salts of azelastine wherein "the weight of azelastine base is 0.003 to 0.5% of the weight of the medicament." As the parties agree, the claimed dosage ranges relate to azelastine as the free base. The parties agree that the salt form at issue in this case — azelastine hydrochloride — is a "physiologically acceptable salt." (D. I. 101-2). The specification teaches that "[t]he formulations of the invention . . .

contain . . . in particular 0.003 to 0.5% (weight/weight) of azelastine (related to the free azelastine base). ***Should the azelastine be present as a salt, the amounts should be recalculated as necessary*** to give the amounts of azelastine itself mentioned above." Ex. B, col. 3, ll. 26-34 (emphases added). The disagreement between the parties with respect to this claim term appears when the medicament is a solution. But there should be no disagreement.

A solution is a type of formulation that is discussed in terms of volume (*e.g.*, milliliters or mls), as opposed to weight (*e.g.*, milligrams or mgs). The specification recognizes that, in the case of solutions, the azelastine dosage should be measured in terms of weight per volume of solution, not weight per weight of the solution. For example, the '194 specification states that "[i]n the case of ***solutions***, the dosage per nostril is, for example, 0.01 to 0.2 ***ml***, in particular 0.05 to 0.15 ***ml***." *Id.* at col. 3, ll. 40-41 (emphases added). Therefore, one of ordinary skill in the art would view the weight/weight percentage in Claim 4 in terms of a weight/volume percentage. The specification explicitly contrasts this calculation to the calculation applicable to powders: "In the case of powders, the concentration of azelastine base is 0.0005 to 2 percent by weight related to the solid carrier substances." Ex. B, col. 3, ll. 37-39.

Unlike Apotex's proposed definition, MedPointe's proposed definition, which "[i]ncludes a 0.0033 to 0.55% (weight/volume) aqueous solution of azelastine hydrochloride," appropriately takes into account that the dosage range in the claim limitation must be adjusted from a weight/weight percentage to a weight/volume percentage when discussing a solution. Given that there is no dispute regarding the dosage in Apotex's aqueous solution product, this issue is appropriate for resolution as a matter of claim construction.

For at least these reasons, MedPointe respectfully requests that the Court construe the phrase "the medicament contains 0.003 to 0.5% (weight/weight) of azelastine or an amount of a

physiologically acceptable salt of azelastine which contains 0.003 to 0.5% (weight/weight) azelastine" in Claim 4 of the '194 patent to include in its definition "0.0033 to 0.55% (weight/volume) aqueous solution of azelastine hydrochloride."

F. "Aqueous Solution"

The phrase "aqueous solution" in Claim 7 of the '194 patent should be given its plain and ordinary meaning as understood by a person of ordinary skill in the art. The dictionary definition of "aqueous solution" is "[a] solution with the solvent as water." Ex. J, McGraw-Hill Dictionary of Chemical Terms 31 (1985). The same dictionary defines "solution" as "[a] single, homogeneous liquid, solid, or gas phase that is a mixture in which the components (liquid, gas, solid, or combinations thereof) are uniformly distributed throughout the mixture." *Id.* at 400. Given these straightforward definitions, MedPointe contends that no special claim construction is necessary.

Again seeking to broaden the claims for its invalidity arguments, Apotex insists upon proposing a strained construction that is not supported by plain meaning or the patent specification. Apotex concedes that the term should be given its ordinary meaning, but seeks to include the additional language "a formulation wherein the excipients, preservatives, and/or ***active ingredients*** are dissolved in a solvent and the solvent is water." The plain meaning of "aqueous solution," however, simply does not require the addition of excipients, preservatives, or active ingredients. In addition, contrary to Apotex's definition, nowhere does the patent suggest a therapy combining azelastine with any other active ingredient. Claim 7 is dependent on Claim 1, which contemplates only an active ingredient that is "a member selected from the group consisting of azelastine and its physiologically acceptable salts." Ex. B, col. 8, ll. 4-6. Neither the specification nor the claims contemplate the addition of any other active ingredient.

Similarly, the specification supports that the "aqueous solution" of the invention claimed

in the '194 patent contains only aqueous solutions with a single active ingredient — *i.e.*, azelastine or one of its physiologically acceptable salts. *See* Ex. B, Abstract ("A medicament . . . which contains ***as active ingredient azelastine or a physiologically acceptable salt***") (emphases added); col. 2, ll. 3-5 ("the object of the present invention is to provide a well tolerated and improved remedy ***based on azelastine or its salts***....") (emphases added); col. 6, ll. 7-9 ("Example 1: Nasal spray or nasal drops or eye drops with 0.1% ***azelastine hydrochloride as active ingredient***") (emphases added)

Apotex's proposed construction also again violates the doctrine of claim differentiation. Another claim of the '194 patent specifically claims the use of preservatives (Claim 5). Adding preservatives to this construction could render that claim superfluous. This is improper and an independent basis to reject Apotex's proposed construction. *See AllVoice Computing PLC v. Nuance Communications, Inc.*, 504 F.3d 1236, 1247 (Fed. Cir. 2007) (stating that "claim differentiation takes on relevance in the context of a claim construction that would render additional, or different, language in another independent claim superfluous.")

For at least these reasons, MedPointe respectfully contends that the phrase "aqueous solution" in Claim 7 of the '194 patent requires no construction.

G. "Solution"

The term "solution " as in Claim 8 of the '194 patent should also be given its ordinary meaning. As stated above, the dictionary definition of "solution" is "[a] single, homogeneous liquid, solid, or gas phase that is a mixture in which the components (liquid, gas, solid, or combinations thereof) are uniformly distributed throughout the mixture." Ex. J, McGraw-Hill Dictionary of Chemical Terms 400 (1985). No claim construction is required to further elucidate this term.

As with "aqueous solution," Apotex again proposes a construction not supported by the

plain meaning or the patent specification. Apotex concedes that the term should be given its ordinary meaning, but states that it should include "a formulation for direct application to the nasal tissues, wherein any excipients, a preservative and ***active ingredients*** are dissolved in a solvent and the preservative is either sodium-2-(ethylmercurithio)-benzoate or akylbenzyldimethyl ammonium chloride in the stated concentrations." (emphases added) First, the term "solution" says nothing about excipients, preservatives or active ingredients. Second, contrary to Apotex's proposed definition, nowhere in the patent is it suggested that the claimed invention includes a therapy combining azelastine with any other active ingredient. Claim 8 is dependent on Claim 1, which contemplates only an active ingredient that is "a member selected from the group consisting of azelastine and its physiologically acceptable salts." Ex. B, col. 8, ll. 4-6. Neither the specification nor the claims contemplate the addition of any other active ingredient.

Similarly, the specification supports that "solution" as used in the '194 patent would include only a single active ingredient — namely, azelastine or one of its salts. *See* Ex. B, Abstract ("A medicament . . . which contains ***as active ingredient azelastine or a physiologically acceptable salt***") (emphases added); col. 2, ll. 3-5 ("the object of the present invention is to provide a well tolerated and improved remedy ***based on azelastine or its salts***....") (emphases added); col. 6, ll. 7-9 ("Example 1: Nasal spray or nasal drops or eye drops with 0.1% ***azelastine hydrochloride as active ingredient***") (emphases added).

Lastly, Apotex's proposal to include "***any*** excipients" runs afoul of the definition of "a medicament." If the excipients are not safe, effective and tolerable, they could not be included in "a medicament."

For at least these reasons, MedPointe respectfully contends that the term "solution " in

Claim 8 of the '194 patent requires no construction.

H. "Applied By Spraying"

The phrase "applied by spraying" in Claim 9 of the '194 patent should be construed to mean "Delivering a fixed volume (typically, 50 to 150 microliters) of an aqueous solution to nasal tissues by aerosolizing that solution into a fine mist (typically with the size of most droplets falling in the range of 10 to 250 micrometers) targeted to those tissues. Excludes application to the eye and excludes application of drops to the nose." MedPointe's proposed construction is supported by the specification, which only discloses delivery of the drug by spraying the drug in an aqueous solution that is delivered in a certain volume and with a certain particle size to nasal tissues.

The '194 patent discloses many different ways of delivering azelastine to a patient's nose, including by nasal sprays and drop. Nasal sprays and nasal drops are distinguishable, based on, *inter alia*, the equipment used to deliver the drug to the patient and the form of the drug/solution to be used. A "drop" is what comes out of a medicine dropper or pipette, and is individually dropped into the nose. A "spray" is a type of aerosol, which is a dispersion of droplets — much smaller than drops — in air that comes out of a spray nozzle that is targeted to nasal tissues. These methods of delivery are distinguishable and have different accompanying advantages and disadvantages. Indeed, the specification refers to sprays and drops separately, *see, e.g.*, Ex. B, col. 2, ll. 14-17; col. 2, l. 23, and the patent specifically references both mechanisms of drug delivery in separate claims, Ex. B, col. 8, ll. 34-37.

The specification supports MedPointe's proposed construction that requires delivery of a fixed volume of an aqueous solution of typically 50 to 150 microliters (µl). For instance, Example 1 in the patent describes a nasal spray that sprays about 140 microliters (µl) per actuation. Ex. B, col. 6, ll. 26-28. *See also* Ex. B, col. 3, ll. 40-41 ("[i]n the case of solutions,

the dosage per nostril is, for example, 0.01 to 0.2 ml, in particular 0.05 to 0.15 ml" or 50 to 150 µl). This construction is also supported by the extrinsic evidence. A treatise in the pertinent art states that a "nasal pump can be designed to dispense a dose of 50 to 150 µl." Ex. K, Aerosols in Medicine (1985) at A06311. Nothing in the specification indicates that the claimed invention covers delivery of a fixed volume of drug outside the range of 50 to 150 µl.

The specification also supports MedPointe's proposed construction that requires delivery of an "aqueous solution." The specification states:

> The preferred embodiment of the invention is a sterile and stable ***aqueous solution*** of azelastine or one or more of its salts which can be used in the form of drops, ointments, creams, gels, insufflatable powders or, ***in the particularly preferred embodiment, in the form of a spray (preferably a nasal spray)***.

Ex. B, col. 2, ll. 12-17 (emphases added). In addition, Example 1 of the '194 patent demonstrates that "applied by spraying" refers to an aqueous solution. *See id.* at col. 6, ll. 19-31 ("The solution obtained is diluted . . . with water . . . . azelastine hydrochloride [is] sprayed into the nose . . . in the form of a solution."). In addition, extrinsic evidence supports that a person of ordinary skill in the art would understand "applied by spraying" to be limited to aqueous solutions. *See* Ex. I, Remington's Pharmaceutical Sciences (1985) at 1500 ("Nasal solutions are usually ***aqueous solutions*** which are designed to be administered to the nasal passages in drops or ***spray form***.") (emphases added).

The term "applied by spraying" should be construed to be limited to nasal tissue application. According to the patent, the delivery method of spraying is only used for nasal tissue applications. Indeed, the specification discloses several "nasal forms" of treatment, but only one form of treatment for the eyes — the "eye drop." *See* Ex. B, col. 3, ll. 34-36 ("In the case of the ***eye drops***, the same azelastine concentrations apply as in the case of the ***nasal forms***.") (emphases added); col. 3, l. 44 (In the case of use at the eye (eye drops) the dosage

is...). Examples 1-4 in the specification teach multiple nasal forms (i.e., nasal spray, nasal drops, nasal ointment, and dosage aerosol), but again only one form for the eyes (the eye drop). The patent provides no suggestion that the claimed treatment can be applied to the eye by spraying.

Extrinsic evidence confirms that the claim term "applied by spraying" excludes application to the eyes.

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The specification also supports MedPointe's proposed construction that requires "aerosolizing that solution into a fine mist." The specification states "[f]or the nasal application a solution or suspension is preferably used which is applied as an aerosol, i.e., in the form of a fine dispersion in air . . . ." Ex. B, col. 5, ll. 18-20. MedPointe's proposed construction, which requires that the typical size of the droplets dispensed fall within the range of 10 to 250 micrometers (microns), is also supported by intrinsic and extrinsic evidence. The specification clearly indicates that the claimed invention is intended to treat conditions of the nose and eye, but not the lung. *See* Ex. B, col. 1, ll. 39-40 (discussing "[e]limination or marked relief" of rhinitis). A person of ordinary skill in the art would understand that a nasal spray, designed to treat disorders of the nose, should contain droplets that fall within the range of 10 to 250 micrometers. Droplets that are smaller than 10 micrometers will travel from the nose into the lungs, and thereby negate the therapeutic value of the nasal spray. *See* Ex. L, Remington's Pharmaceutical Sciences 1491 (14th ed. 1970) ("The spray device should produce relatively coarse droplets if the action of the drug is to be restricted to the upper respiratory tract. Fine droplets tend to penetrate farther into the respiratory tract than is desirable."); Ex. M, Physicians' Desk Reference 2005 (1987) (describing that, for Nasalide®, "[t]he size of the droplets produced by the unit is in excess of 8 microns to facilitate deposition on the nasal mucosa."); Ex. N, A.S. Harris et al., 77 Journal of Pharmaceutical Sciences 405-408 (1988) (showing a particle size distribution of spray droplets from a pre-metered spray pump device for an aqueous solution that ranges from about 14 micrometers to 260 micrometers in size).

MedPointe's proposed construction, which requires that the typical size of the droplets dispensed fall within the range of 10 to 250 micrometers, excludes application of "drops" to the

nose. Again, this definition is supported by intrinsic and extrinsic evidence. The patent could not be more clear that droplets, which are produced by sprays, are different from drops, which are produced by droppers. For example, Claim 9 covers a method of treatment in which the medicament is applied by spraying, and Claim 10 covers a method of treatment in which the medicament is applied as drops. Since "applied by spraying" and "applied as drops" are claimed separately, the terms are presumed to have different meanings. *See Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1123 (Fed. Cir. 2004) ("'different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope'").

Moreover, the specification consistently distinguishes between a "spray" and a "drop." The patent discloses as preferred embodiments of the invention "stable aqueous solution of azelastine or one or more of its salts which can be used in the form of ***drops***, ointments, creams, gels, insufflatable powders or, in a particularly preferred embodiment, in the form of a ***spray*** (preferably a nasal spray)." Ex. B, col. 2, ll. 14-17 (emphases added). In further distinguishing between "drops" and "sprays," the specification provides for the use of azelastine, "[t]hrough the use of nasal drops ***or*** a nasal spray. . . ." *Id.* at col. 2, l. 23.

Similarly, Example 1 of the '194 patent distinguishes between "nasal spray," "nasal drops" and "eye drops." Specifically, a nasal spray is applied by using a pump, whereas nasal drops and eye drops are applied with a dropper pipette. In the paragraph of Example 1 describing the use of ***spray pumps***, it further discusses the amount of azelastine "***sprayed into the nose.***" *Id.* at col. 6, ll. 19-31 (emphases added). In contrast, the second paragraph of Example 1 teaches methods for application of drops: "[i]f the above obtained filtrate is filled into the ***bottles with dropper pipettes conventionally used for nasal drops or eye drops, the solution can be***

dripped into the nose or eye using a dropper pipette." *Id.* at col. 6, ll. 32-35 (emphases added).

Various publications confirm that "sprays" are different from "drops." For example, Remington's Pharmaceutical Sciences notes that "[n]asal solutions are usually aqueous solutions which are designed to be administered to the nasal passages in ***drops or spray form.***" Ex. I, Remington's Pharmaceutical Sciences 1500 (17th ed. 1985) (emphases added). Another publication, Aerosols In Medicine, states that "[d]rugs can be given in the nose as aerosols from pressurized aerosols and from metered-dose pump sprays, as solutions from drop bottles, and as powders inhaled from special devices." Ex. K, Aerosols In Medicine: Principles, Diagnosis and Therapy (1985) at A06243.

The difference between sprays and drops is further demonstrated by the fact that the size of droplets in a spray is more than an order of magnitude smaller than the size of drops produced by a dropper. According to Remington's Pharmaceutical Sciences and the United States Pharmacopeia, a medicine dropper delivers 20 drops weighing on average a total of about 1 gram, equivalent to about 1 cubic centimeter of water. Ex. I, Remington's Pharmaceutical Sciences 82 (17th ed. 1985); Ex. O, The United States Pharmacopeia 1329 (16th ed. 1985).

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Apotex proposes a construction of "applied by spraying" that is not supported by the claims or the specification. The intrinsic evidence demonstrates that "applied by spraying" cannot, as Apotex contends, include non-aqueous solutions, suspensions and powders. Since Claims 9, 10 and 11 specifically claim modes of application by spraying, drops, and powders, respectively, "applying by spraying" cannot include applying by powder or by drops, as Apotex's proposed construction suggests, under the doctrine of claim differentiation. *See Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1123 (Fed. Cir. 2004) ("'different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope'").

Moreover, during the prosecution of the '194 Patent, the applicant distinguished "applied by spraying" in Claim 9 from a powder. According to the applicant: "The invention is claimed in claim 1 as a method which comprises applying azelastine directly to the nasal tissues or to the conjunctival sac of the eye. Claims 2-8 relate to more preferred features of the pharmaceutical compositions containing azelastine which is applied in accordance with the method of claim 1. ***Claims 9-11 relate to more preferred modes of application*** of the azelastine-containing composition." Ex. E, MP0113 (emphases added).

Furthermore, as explained above, Apotex's proposed construction is wrong on other grounds as well. First, it includes spray delivery "directly to the . . . conjunctival sac of the eyes," which the specification does not contemplate or disclose and which Apotex's own expert agrees does not exist for the treatment of allergies.

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Second, Apotex's proposed construction states that a spray delivers "drops," which the

claims, specification and extrinsic evidence demonstrate is a different method of delivery and therefore not encompassed by the term "applied by spraying."

For at least these reasons, MedPointe respectfully requests that the Court construe the phrase "applied by spraying" in Claim 9 of the '194 patent to mean: "Delivering a fixed volume (typically, 50 to 150 microliters) of an aqueous solution to nasal tissues by aerosolizing that solution into a fine mist (typically with the size of most droplets falling in the range of 10 to 250 micrometers) targeted to those tissues. Excludes application to the eye and excludes application of drops to the nose."

IV. Claim 12

In an effort to narrow and focus the issues, MedPointe is no longer asserting Claim 12 of the '194 patent. MedPointe informed Apotex of this fact on December 17, 2007. Accordingly, MedPointe proposed to Apotex that the parties submit an Amended Joint Claim Construction Statement, to avoid troubling the Court with construing three terms that are no longer at issue. These three terms are listed as the last three disputed terms in the original Joint Claim Construction Statement (D.I. 101).

Inexplicably, Apotex refused, and indicated that it still intends to ask the Court to construe these three terms. To the extent that Apotex follows through with this stated intention, MedPointe reserves the right to submit opposing materials regarding these terms in its responsive claim construction brief on January 9, 2008.

CONCLUSION

For the foregoing reasons, MedPointe respectfully requests that the Court adopt its proposed constructions of the disputed claim terms and phrases as set forth herein.

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